K091951 (pg 1/2)

(510(k) Summary)

FEB 19 2010

Product: OSSplate™ HammerLock™

BioMedical Enterprises, Inc. (BME) intends to introduce an addition to the OSSplate™ line of the OSStaple™ Staple System.

Submitter Information

BioMedical Enterprises, Inc.
14785 Omicron Drive, Ste. 205
San Antonio, Texas 78245
Telephone: (210) 677-0354
Contact: Joe W. Soward

Date Prepared: June 26, 2009

Classification name:	Smooth or Threaded Metallic Bone Fastener
Common/Usual Name:	Intramedullary Bone Fastener
Proprietary Name:	Hammerlock™

Intended Use:

The HammerLock™ is indicated for small bone reconstruction and fusion such as inter-digital fusion of fingers and toes.

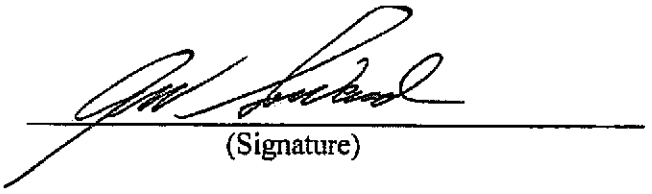
Device Description

The HammerLock™ is an addition to the OSSPlate™ line and is designed for use as an intramedullary bone fixation device. The OSSPlate™ is situated on the bone with the prongs extending through the cortex and in its final configuration the prongs are deflected inward to create a clamping force. With the HammerLock™ the device is situated in the intramedullary space with the prongs extending into the cancellous bone and in the final configuration the prongs are deflected outward to create a compressive force. Two models of the HammerLock™ are provided for physician choice, the HammerLock™ X-Type and HammerLock™ Loop. Both exhibit similar test results to the predicate devices. The HammerLock™ models transformed to their final configuration by body heat alone.

Substantial Equivalence:

The HammerLock™ is substantially equivalent to Memometal Technologies (MMI-USA) SmartToe™.

The FDA has classified these equivalent devices as Class II devices (e.g. 21 CFR, 888.3040). The HammerLock™ is a Class II medical device.



(Signature)

Joe W. Soward
Director, Quality Assurance and Regulatory Affairs
BioMedical Enterprises, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

FEB 19 2010

Biomedical Ent., Inc.
% Mr. Joe W. Soward
14785 Omicron Dr., Suite 205
San Antonio, Texas 78245

Re: K091951
Trade/Device Name: HammerLock™
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY
Dated: December 15, 2009
Received: December 16, 2009

Dear Mr. Soward:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Name: Hammerlock

Indications for Use

The HammerLock™ is indicated for small bone reconstruction and fusion such as in the phalanges of the fingers and toes.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091951